“STUDY TO ASSESS THE EFFECTIVENESS OF YOGA ON STRESS LEVEL AND QUALITY OF LIFE OF BREAST CANCER PATIENTS UNDERGOING CHEMOTHERAPY”

SYNOPSIS SUBMITTED

by

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Background of the study

Among cancer of different organs in the body, the carcinoma of the breast is highest in occurrence worldwide, after lung cancer. It occurs mostly in women. In 2012 there were over 1.67 million women who were newly diagnosed with breast carcinoma. (GLOBOCAN 2012)

A survey conducted by Bag A. et al. in the year 2012 in Nainital Uttarakhand, reported that lung cancer was the highest among types of cancer in that region. Among women the incidence of breast cancer was highest followed by cervical and ovarian cancers. Cancers caused by tobacco and alcohol use were common in males e.g., lungs, larynx, oropharynx, oral cavity, and esophagus. (Bag A et al. 2012)

The term, Health Related QOL (HR-QOL) is individual's perception of physical, emotional, social and cognition aspect of health either negatively and positively. (Moinpour C 1994)

Treatment of cancer and cancer itself cause many side effects and complications, which influence the quality of life (QOL) and cause a considerable consequence on Health Related QOL (HR-QOL) in common. (Johnson B et al 2008)

Greene D et al. (1994) studied the adverse effects and disturbance in activities of daily living caused by three chemotherapeutic drug regimen groups reported by eighty six female patients receiving treatment for cancer of the breast. The most commonly reported side effects were tiredness, vomiting, loss of appetite, changes in taste, and pain in head. The incidences of these side effects were similar for these regimen groups. Fatigue was significantly associated with duration of receiving the drugs. Patients also reported that they experienced disturbance in activities of daily living at a moderate level.

So W.K et al. (2009) researched the effectiveness of anxiety and depression on quality of life of women who were undergoing treatment for carcinoma breast i.e. chemotherapeutic drugs and radiotherapy. It was observed that level of anxiety or apprehension and depression or sadness was greater in study participants who were receiving chemotherapy in comparison to

those receiving radiotherapy. Anxiety and depression had unfavorable effects on overall and different areas of QOL of these patients taking treatment for breast cancer.

A study by Yazdani F (2014) observed that short term yoga was effective in improving adverse effects of chemotherapy such as cognitive performance, sleep patterns and reduction of fatigue, sickness and vomiting in cancer patients.

Wesa K et al. (2008) stated that supportive or complementary therapies are easy to administer, economical, and useful in reducing the adverse effects of cancer treatment and helpful in enhancing the quality of life of patients with cancer. Thorough scientific research done on these has confirmed that complementary therapies are effective in reducing the symptoms in cancer patients, may it be physical or emotional in nature. They have less risk and more benefits and permit cancer survivors to cope with their personal care more effectively.

This research was carried out to assess the effectiveness of yoga on the stress level and quality of life of breast cancer patients undergoing chemotherapy.

Study objectives were -

1. To determine the effectiveness of yoga on the stress level of breast cancer patients undergoing chemotherapy
2. To determine the effectiveness of yoga on the quality of life of breast cancer patients undergoing Chemotherapy.

Hypothesis

H_1- There would be a significant decrease in the stress level scores of breast cancer patients undergoing chemotherapy, in the experimental group compared to those in the control group after implementation of yoga at $p<0.05$ level of significance.

H_2- There would be significant improvement in the quality of life scores of breast cancer patients undergoing chemotherapy, in the experimental group compared to those in the control group after implementation of yoga at $p<0.05$ level of significance.

Variables: The variables in this study were demographic & clinical variables. The independent variable was yoga intervention. The dependent variables were stress level and quality of life of breast cancer patients receiving chemotherapy.

Methodology: A randomized clinical controlled trial with a time series design was adopted in the present study. A consecutive sampling technique was done to recruit 100 breast cancer patients who had had operated for breast cancer as primary treatment and fulfilled the eligibility criteria. The recruited patients were randomly allocated to the control (N=52) and the experimental (N=48) groups by concealed randomization. Informed written consent was taken from the study participants and their accompanying family member. The patients in experimental group were taught yoga, comprising of diaphragmatic breathing, systematic relaxation, alternate nostril breathing and joints & glands, neck & shoulder exercises during the first cycle of chemotherapy. Patients were instructed to practice yoga daily at home twice a day. They were given a booklet having information on the above stated yoga intervention. Once a week reminder calls were done. They were supervised while practicing yoga during their next visits for six sessions of chemotherapy. The patients in the control group were given routine care. Assessment of stress level was done by Anxiety, Depression and Stress Scale and quality of life by EORTC QLQ C 30 & QLQ BR 23 during the first cycle of chemotherapy and thereafter every 21 days in each cycle from the second through the sixth cycle.

The data was analyzed by using SPSS (version 20). Since variables followed a skewed distribution, two groups were compared by using non parametric Mann-Whitney test. Within group effect was estimated by the Friedman test. The Wilcoxon Signed rank test was used to find the difference from the baseline score**.** Statistical significance was established at 0.05 level.

Results: In the present study breast cancer patients in the control group and the experimental group were homogeneous with regard to their socio-demographic and clinical variables.

- It was observed that at the baseline (cycle one) patients in the control and the experimental groups were homogeneous in terms of their anxiety, depression, stress and quality of life scores.

Analysis of Anxiety, Depression & Stress scores

- The average anxiety scores of participants in the control group increased slightly from the baseline in all six cycles, showing significant difference within the group. Whereas the anxiety scores of participants in the experimental group remained almost the same throughout the six cycles. It was observed that anxiety scores of both groups differed significantly in the second, third and sixth cycles of chemotherapy (p 0.01, p 0.02, p 0.02).
- The mean depression scores of breast carcinoma patients belonging to the control group remained almost the same over a period of six cycles. However the depression scores of the experimental group decreased significantly from the baseline in all six cycles. It was noted that the anxiety scores of both groups differed significantly in the second, third, fourth, fifth and sixth cycles of chemotherapy (p0.02, p 0.02, p 0.02, p0.001, p0.000) respectively.
- The average stress scores of the control group increased significantly from the baseline score in the third and fourth cycles, whereas the stress scores of the experimental group differed significantly from the baseline score in the second, third and fifth cycles. It was observed that stress scores of both groups differed significantly in the third cycle (p 0.01).
- It was concluded that Yoga was effective in maintaining symptoms of anxiety and stress at lower levels and decreasing symptoms of depression in breast carcinoma patients going through chemotherapy in the experimental group in comparison to the control

Analysis of quality of life QLQ C 30

- The Global Health Status average scores decreased significantly in both groups during the period of chemotherapy. However, as the patients in the experimental group continued yoga practice, their global health status scores improved significantly in comparison to the control group ($p<0.05$).

  Functional scores

- The mean scores of the physical function aspect of quality of life for the control group decreased significantly from the baseline score in the second through the sixth cycle, whereas, scores of the experimental group decreased statistically from the baseline only in the fourth cycle, showing that yoga was effective in increasing physical performance of breast carcinoma patients undergoing chemotherapy.

- The average scores of role function of females belonging to the control group decreased significantly from the baseline score in the second through the sixth cycle, whereas, in the experimental group the scores continued to be similar as baseline score (first cycle) through the sixth cycle, showing that yoga was effective in maintaining the role performance of breast malignancy patients undergoing chemotherapy.
- The mean scores of the emotional function of participants of both experimental and control groups decreased significantly from the baseline score in the 3rd, 4th, 5th and the 6th cycles. However, it was observed that the control group had a greater decrease in scores compared to the experimental group. The experimental group exhibited a statistically significant differentiation from the control group in sixth cycle (p 0 .05), showing that yoga was effective in improving the emotional functioning of women with breast carcinoma going through chemotherapy.
- The mean scores of cognitive function of participants of the experimental and the control groups showed a trend of gradual decrease from the baseline scores in the 2nd, 3rd, 4th, 5th and 6th cycles, which was statistically significant. However, the experimental group exhibited a statistically significant differentiation from the control group in the fifth cycle (p 0.03).
- The social function scores of control group exhibited a trend of decrease from the baseline (58. 33±16.99) score in the second through the sixth cycle (37.69±20.51) of chemotherapy, which was statistically significant. Patients in the experiment group also revealed a reduction in mean score from the baseline (59.02±14. 56) score in the second through the fourth cycle (41.30±10.38) cycle. However, the social function average scores of both groups did not differ significantly in any cycle of chemotherapy.

Symptom scores

- The average scores of the fatigue in the experimental and the control groups increased significantly from the baseline score through the sixth cycle. It was observed that fatigue score increased more in control group in comparison to the experimental group. However the experimental group exhibited statistically significant differentiation in comparison to control group in the second through the sixth cycle (p 0.001, p 0.002, p 0.001,p 0.0002, p 0.0000) respectively, showing that yoga was helpful in relieving the fatigue in breast carcinoma clients who were receiving chemotherapeutic drugs.

- The mean scores of the nausea and vomiting in the experimental and the control group increased significantly from the baseline in the second through the sixth cycle. The mean score of the experimental group differed significantly from the control group in third cycle (p 0.02).
- The average scores of insomnia of participants who were in the experimental and the control group increased significantly from baseline score in the second through the sixth cycle. However, the experimental group showed statistically significant differentiation from the control group in the fifth cycle (p 0.01).
- The average scores of loss of appetite of participant who were in the experimental and the control group increased significantly from the baseline score in the second through the sixth cycle. However, the mean scores of the experimental group revealed a statistically significant variation from the control group in the second, fourth, fifth & sixth cycles (p 0.01, p0.006, p 0.01, p0.001) respectively.
- The mean score of constipation of the sample who were in the experimental and the control group increased significantly from baseline score in the second through the sixth cycle. The mean score of the experimental group showed statistically significant variation from the control group in third cycle (p 0.03).
- It was concluded that yoga was effective in relieving the symptoms of fatigue, reducing the nausea & vomiting, insomnia, constipation and improving the appetite of breast cancer patients undergoing chemotherapy in the experimental group in comparison to the control group.
- The mean score of the pain increased significantly in the control group from the baseline score in the second, fifth and the sixth cycles and in the experimental group scores increased significantly from the baseline score in the fourth cycle. The experimental group exhibited no statistically significant variation from the control group in any of the cycles.
- The mean scores of dyspnea increased significantly in both the groups during the second cycle and decreased gradually in the third through the sixth cycle. However, the experimental group had no statistically significant differentiation from the control group in any of the cycles.

- The average scores of gastrointestinal symptom diarrhea in sample belonging to the experimental group did not differ significantly from the control group in all six cycles of chemotherapy.
- Study findings showed that yoga had no influence in reducing the scores of pain, dyspnea and diarrhea significantly in patients undergoing chemotherapy.
- The patients of both groups had financial difficulties throughout the period of chemotherapy.

Analysis of EORTC QLQ BR-23

Functional scores

- The mean scores of perception of body image revealed a trend of decrease in scores in both groups. The mean scores of those patients belonging to the experimental and the control group decreased significantly from the baseline score in the second through the sixth cycle. However, the experimental group revealed statistically significant variation from the control group in the third and fifth cycles (p 0.03, p 0.03).
- The mean scores of future perspectives of patients in the control group decreased in the second through the sixth cycle compared to the baseline score. In the experimental group mean scores increased significantly in the second through the sixth cycle compared to the baseline score. The experimental group exhibited a significant differentiation from the control group in the second through the sixth cycle of chemotherapy (p 0.03, p0.001, p0.03, p0.00, p0.000,p 0.000).
- The study findings concluded that yoga was effective in improving the perception of body image and future perspectives of breast cancer patients who were undergoing chemotherapy in the experimental group in comparison to the control group.
- A greater decrease in mean scores of sexual functioning and sexual enjoyment was observed in patients of both groups during the period of chemotherapy.

Symptom scores

- The mean scores of systemic therapy side effects of participants belonging to the experimental and control group increased significantly compared to baseline score in the second through the sixth cycle. However, significant difference between the

experimental group and the control group was observed in the fourth and sixth cycles (p 0.008& p0.02).

- The breast symptoms average scores of the control group decreased significantly from the baseline score in the second, fifth and the sixth cycles. However, the scores of experimental group decreased significantly compared to the baseline score in the second through the sixth cycle. A significant difference between both groups was observed in the third and sixth cycles (p 0.0001, p 0.01).
- The average arm symptoms scores of participants in both groups decreased significantly compared to the baseline score in the third, fourth, fifth and sixth cycles. A significant difference between the experimental group and control group was observed in the third and the sixth cycles (p 0.003, p 0.01).
- The average scores regarding upset by hair loss in patients of the experimental and control group increased significantly from second cycle score (baseline) in the third through the sixth cycle. However the experimental group revealed a significant variation from the control group only in sixth cycle (p 0.02).
- Study findings showed that yoga was effective in reducing the systemic therapy side effects, symptoms of breast & arm and grief caused by alopecia i.e. hair loss, among women who were undergoing chemotherapy for breast cancer and belonged to the experimental group in comparison to the control group.

  This research revealed that yoga was effective in reducing the depression level and improving the quality of life of breast cancer patients who were undergoing chemotherapy. Therefore, it was recommended that diaphragmatic breathing, systematic relaxation and alternate nostril breathing, which are simple yogic relaxation techniques should be incorporated as Complementary therapy in the treatment of cancer.

Implication: The present study has several implications for clinical practice

1. The practical contribution of the present research is that it has provided empirical data on symptoms of anxiety, depression and stress expressed by breast cancer patients as they went through the period of chemotherapy.

2. It has been revealed by the present study that adverse effects of chemotherapy are detrimental to the quality of life of women with breast cancer during the period of chemotherapy.
3. This study provided understanding that yoga was useful in reducing the symptoms of depression and helped in maintaining symptoms of low levels of anxiety and stress in breast cancer patients going through chemotherapy.
4. The study also demonstrated that yoga was effective in reducing the adverse effects of chemotherapy and improving the quality of life of women with breast cancer.

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